

UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
FLORENCE DIVISION

Accident, Injury and Rehabilitation, PC,) C/A No. 4:18-cv-02173-DCC
d/b/a Advantage Health and Wellness,)
)
 Plaintiff,)
)
 v.) **OPINION AND ORDER**
)
 Alex M. Azar, II, Secretary of the United)
 States Department of Health and)
 Human Services; and Seema Verma,)
 Administrator for the Centers for)
 Medicare and Medicaid Services,)
)
 Defendants.)

This matter comes before the Court on Plaintiff's Motion for Temporary Restraining Order and Preliminary Injunction. ECF No. 5. On August 8, 2018, the Court directed Plaintiff to serve Defendants with the Complaint and Motion. ECF No. 8. On August 13, 2018, the Court held a telephonic status conference with the parties to discuss the pending Motion. ECF No. 14. During the conference, the Court ordered the parties to consult within ten days to discuss the possibility of settlement negotiations and directed the parties to file a joint status conference at the conclusion of the ten-day period. *Id.* On August 20, 2018, the parties filed a Joint Status Report indicating "the Parties have agreed to engage in direct settlement negotiations and, if necessary, mediation through a third party neutral." ECF No. 19. On August 21, 2018, the Court issued a Temporary Restraining Order restraining and enjoining Defendants from withholding Medicare payments to Plaintiff or attempting or initiating any other collection efforts. ECF No. 20. The Court then scheduled a hearing on Plaintiff's Motion for Preliminary Injunction. ECF No. 21.

Thereafter, Defendants filed a Response in Opposition to Plaintiff's Motion, Plaintiff filed a Reply, and Defendants filed a Sur Reply. ECF Nos. 23, 24, 26. The Court held a hearing on Plaintiff's Motion on August 31, 2018, and took Plaintiff's Motion under advisement. ECF No. 27. The Court also found good cause to extend the Temporary Restraining Order until September 18, 2018, and directed the parties to investigate a resolution to this matter.¹ It appearing that the parties have not come to a resolution of this matter, the Court now converts the Temporary Restraining Order to a Preliminary Injunction.

BACKGROUND

I. Overview of Medicare Appeals System

In 1965, Congress enacted Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq., known as the Medicare Program. Entitlement to Medicare is based on age (65 or older), disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426-1. Medicare is comprised of Parts A, B, C, and D. Part B is medical insurance that authorizes payment of federal funds for health services, including physician, laboratory, outpatient, diagnostic, and radiology services. See 42 U.S.C. § 1395k; 42 C.F.R. § 410.10.

The Secretary of Health and Human Services ("HHS") has overall responsibility for the administration of Medicare. Within HHS, the responsibility for the administration of Medicare has been delegated to the Centers for Medicare & Medicaid Services ("CMS"). To assist in the administration of Medicare Part B, CMS initially contracted with carriers

¹ The Court further extended the temporary relief until September 27, 2018, or until the Court ruled on Plaintiff's Motion, whichever occurred first. ECF No. 28.

or fiscal intermediaries. Carriers, typically private insurance companies, were largely responsible for processing and paying Part B claims. 42 C.F.R. §§ 421.1–421.3.

Beginning in November 2006, Medicare Administrative Contractors ("MACs") began replacing carriers and fiscal intermediaries. See 42 U.S.C. § 1395kk-1; 42 C.F.R. § 421.400 *et seq.*; 71 F.R. 67960-01, at 68181 (Nov. 24, 2006). MACs generally act on behalf of CMS to process and pay Part B claims and perform administrative functions on a regional level. Since at least 2006, Palmetto GBA served as the Medicare carrier and fiscal intermediary for South Carolina until May 2010, when Palmetto GBA was awarded a contract to serve as South Carolina's MAC for Part B claims.

Medicare only covers medically necessary items or services, excluding from coverage "any expenses incurred for items or services [...] which [...] are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). After a hospital or healthcare provider performs Medicare-eligible services, it submits a claim for reimbursement to the MAC, which makes a determination of the medical necessity of the claim.

If the MAC denies a claim, a provider can engage in a four-level administrative appeal process, followed by judicial review. *Am. Hosp. Assoc. v. Burwell*, 812 F.3d 183, 185 (D.C. Cir. 2016). First, the provider presents its claim to the MAC for a "redetermination." *Id.* (citing 42 U.S.C. § 1395ff(a)(3)(A), (a)(3)(C)(ii)). If the MAC denies the "redetermination," the provider can seek "reconsideration" by a Qualified Independent Contractor ("QIC"). 42 U.S.C. § 1395ff(c). Both of these review processes are overseen by CMS. *Burwell*, 812 F.3d at 185. "If the provider remains unsatisfied, and if its claim

exceeds \$150, it may continue to the third stage: de novo review by an administrative law judge, including a hearing." *Id.* (citations omitted). "This stage of the process is overseen by the Office of Medicare Hearings and Appeals ["OMHA"], which houses ALJs and their support staff, and which is funded by a separate appropriation. *Id.* at 185–86 (citations omitted). The final administrative appeal stage involves de novo review by the Medicare Appeals Council, which is a division of the Departmental Appeals Board ("DAB"). *Id.* at 186. "Although the DAB has authority to hold a hearing, it does so only if there is an extraordinary question of law/policy/fact." *Id.* (quotation omitted). Only after a party exhausts these administrative appeals may it seek judicial review in federal court.

In order to streamline the appeals process, there are statutory time frames for each step of the process. Redetermination by the MACs shall be conducted within sixty days. 42 U.S.C. § 1395ff(a)(3)(C)(ii). QICs shall conduct and decide reconsiderations within sixty days. *Id.* § 1395ff(c)(3)(C)(i). ALJs "shall conduct and conclude a hearing . . . and render a decision within ninety days," though the appealing provider may waive this deadline. *Id.* § 1395ff(d)(1)(A), (B). Finally, the DAB must make a decision or remand the case to the ALJ for reconsideration within ninety days. *Id.* § 1395ff(d)(2)(A). If these time periods are complied with, appeals will proceed through the administrative process within approximately a year. The statutory scheme does, however, prescribe consequences for failure to meet several of the deadlines. "In a process commonly referred to as escalation, a provider that has been waiting for longer than the statutory time limit may advance its appeal to the next stage." *Burwell*, 812 F.3d at 186 (internal quotation marks omitted).

"For years, the administrative appeal process functioned largely as anticipated,

with its various stages typically completed within the statutory time frames." *Id.* (citing *Am. Hosp. Ass'n v. Burwell*, 76 F. Supp. 3d 43, 46 (D.D.C. 2014)). Then, in 2010, the Secretary of HHS implemented the Medicare Recovery Audit Program, which is designed "for the purpose of identifying underpayments and overpayments and recouping overpayments." 42 U.S.C. § 1395ddd(h)(1). In order to accomplish this task, the Secretary of HHS entered into contracts with Recovery Audit Contractors ("RACs"), who are paid on a contingency basis for collecting overpayments. *Burwell*, 812 F.3d at 186. Additionally, CMS uses Zone Program Integrity Contractors ("ZPICs") to review post-payment claims. *San Bois Health Servs., Inc. v. Hargan*, No. CIV-14-560-Raw, 2017 WL 5140519, at *1 (E.D. Okla. Nov. 6, 2017). ZPICs frequently use statistical sampling in order to determine the total amount of a provider's overpayments that must be recouped. *Id.* The Recovery Audit program has been quite successful in recouping overpayments. *Burwell*, 812 F.3d at 187. "But because RAC denials are appealable through the same administrative process as initial denials, the RAC program has contributed to a drastic increase in the number of administrative appeals." *Id.* "Between RAC and non-RAC appeals, OMHA currently receives many more cases than it can process in a timely fashion." *Id.*

The backlogged administrative appeals process provides a number of inherent problems for medical providers. But during the first two levels of the appeals process, the status quo remains and the Government cannot begin recouping the money that it is allegedly owed for overpayments. Once a medical provider requests a hearing before the ALJ, however, the Government has the discretionary authority to recoup the alleged overpayments while the appeal is pending, often for several years before the provider is

even afforded a hearing. 42 U.S.C. § 1395ddd(f)(2). It is precisely this issue that brings Plaintiff before the Court in this case.

II. Plaintiff's Claims

Plaintiff is a chiropractic practice that provides “medical, chiropractic and holistic care, including wellness and whole-body treatment for patients in the Florence and greater Piedmont area of South Carolina.” ECF No. 5-2 at 2. Plaintiff participates in the Medicare system and a substantial percentage of its revenue comes from Medicare reimbursements. *Id.* “Prior to 2015, [Plaintiff] earned annual gross revenues of approximately \$6.8 million.” *Id.* Medicare reimbursements constituted thirty-one percent (31%) of those gross revenues. *Id.*

On or about September 4, 2012, AdvanceMed, the ZPIC for South Carolina, opened an investigation into Plaintiff’s medical billing. ECF No. 1 at 2. On July 1, 2013, AdvanceMed conducted an unannounced audit of Plaintiff’s facility in Florence and notified Plaintiff that it was reopening claims made within the prior four years. *Id.* The Notice of Review requested Plaintiff “provide every document and record supporting billing for 15 Medicare beneficiaries between June 2012 and April 2013.” *Id.* at 2. Plaintiff provided the documentation, and, on November 3, 2014, AdvanceMed issued a Notice of Suspension of Medicare Payments to Plaintiff. *Id.* The Notice of Suspension “stated a post-payment review of 25 Medicare Part B claims result[ed] in a 97.8% denial rate.” *Id.* at 3.

On December 3, 2014, AdvanceMed requested documents supporting billing for 80 Medicare beneficiaries between September 2010 and September 2014, which AdvanceMed claims constituted a statistically valid sample of Plaintiff’s Part B claims. *Id.*

Plaintiff provided the required documentation. *Id.* AdvanceMed determined that \$2,507.91 of the Part B claims and \$33,710.40 of the DME claims from this known data set should have been denied. ECF No. 5-5 at 2. Based on these numbers, AdvanceMed apparently extrapolated what the overpayments for the entire four-year population of Part B and DME would be. On June 8, 2015, AdvanceMed issued an Overpayment Determination, notifying Plaintiff that its overpayments totaled \$5,627,263.87 for Part B claims and \$1,021,614.05 for Durable Medical Equipment (“DME”) claims. *Id.*

Plaintiff filed appeals with the MACs for Part B and DME claims,² which were denied in September 2015. *Id.* at 4. Palmetto GBA, the Medicare Part B MAC, also notified Plaintiff that CMS “would seek recoupment through offsets of Plaintiff’s continued provider billings” and “notified Plaintiff that \$163,625.36 had been recouped on July 9, 2015.” *Id.* Plaintiff appealed the MACs’ findings to C2C Solutions, Inc., the QIC for South Carolina. *Id.* The QIC issued a partially favorable decision on the Part B and DME claims, overturning the denials on two of the Part B claims and eleven of the DME claims. *Id.*

On March 10, 2016, Plaintiff appealed the QIC’s DME decision to OMHA and requested a full evidentiary hearing before an ALJ. *Id.* On April 4, 2016, Plaintiff appealed the QIC’s Part B decision to OMHA and requested a full evidentiary hearing before an ALJ. *Id.* Plaintiff’s appeals have been pending since that time, and CMS has withheld over \$1.8 million in Medicare payments while Plaintiff is waiting for an ALJ hearing. *Id.* at 5. CMS has also indicated its intent to refer the overpayment collection to the United States Treasury Department. *Id.* at 6.

² CGS, Inc. is the MAC for DME claims in South Carolina. ECF No. 1 at 3.

On August 7, 2018, Plaintiff filed a Verified Complaint for Temporary Restraining Order and Preliminary Injunction with the Court. ECF No. 1. Plaintiff alleges three causes of action: (1) denial of procedural due process; (2) ultra vires; and (3) violation of the Administrative Procedures Act. *Id.* By way of remedy, Plaintiff asks the Court to enjoin Defendants from their recoupment efforts while Plaintiff is waiting for the ALJ hearings it is entitled to by statute. On August 8, 2018, Plaintiff filed a Motion for Temporary Restraining Order and Preliminary Injunction, with numerous attachments and exhibits. ECF No. 5. On August 17, 2018, Plaintiff filed a Supplemental Memorandum in Support of its Motion. ECF No. 16.

On August 27, 2018, Defendants filed a Response in Opposition, which alleges that the Court does not have jurisdiction over this case and further contends that Plaintiff has not met any of the four required elements for issuance of a preliminary injunction. ECF No. 23. Plaintiff filed a Reply on August 29, 2018, and Defendants filed a Sur Reply on August 30, 2018. ECF No. 24, 26. The Court held oral arguments on Plaintiff's Motion on August 31, 2018 and extended the Temporary Restraining Order until September 18, 2018, so that the parties could explore resolution of this case.³ ECF No. 27. It now being apparent that the parties will not be able to resolve this case without Court intervention, the Court turns to the merits of Plaintiff's Motion.

LEGAL STANDARD

A party seeking a preliminary injunction must establish all four of the following criteria: (1) that the party is likely to succeed on the merits of his claim; (2) that the party

³ The Court further extended the temporary relief until September 27, 2018, or until the Court ruled on Plaintiff's Motion, whichever occurred first. ECF No. 28.

is likely to suffer irreparable harm in the absence of a preliminary injunction; (3) that the balance of the equities tips in the party's favor; and (4) that the injunction is in the public interest. *League of Women Voters of N. Carolina v. N. Carolina*, 769 F.3d 224, 236 (4th Cir. 2014) (citing *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). “A preliminary injunction is an extraordinary remedy never awarded as of right.” *Winter*, 555 U.S. at 24 (citing *Munaf v. Geren*, 553 U.S. 674, 689–90 (2008)). The traditional purpose of a preliminary injunction is “to protect the status quo and prevent irreparable harm during the pendency of a lawsuit.” *Di Biase v. SPX Corp.*, 872 F.3d 224, 230 (4th Cir. 2017) (citing *Pashby v. Delia*, 709 F.3d 307, 319 (4th Cir. 2013)). “A preliminary injunction shall be granted only if the moving party clearly establishes entitlement to the relief sought.” *Id.* (citing *Fed. Leasing, Inc. v. Underwriters at Lloyd’s*, 650 F.2d 495, 499 (4th Cir. 1981)).

DISCUSSION

I. Jurisdiction

Defendants contend that the Court does not have jurisdiction over this matter, relying primarily on 42 U.S.C. § 405(g).⁴ Indeed, “[u]nder 42 U.S.C. § 405(g) and (h), federal courts are vested with jurisdiction over only a ‘final decision’ of HHS when dealing with claims ‘arising under’ the Medicare Act.” *Family Rehab., Inc. v. Azar*, 886 F.3d 496, 500 (5th Cir. 2018) (quoting 42 U.S.C. § 405(h)). Typically, this means that a provider may only come to federal court after satisfying all four stages of administrative appeals or appropriately escalating their appeals when necessary. 42 U.S.C. § 405(g); 42 C.F.R. § 405.1132.

⁴ 42 U.S.C. § 405(g) is a provision of the Social Security Act; however, it has been made applicable to Medicare by 42 U.S.C. § 1395ff(b)(1)(A).

There are, however, exceptions to the jurisdictional bar of 42 U.S.C. § 405(g). In *Mathews v. Eldridge*, the Supreme Court of the United States first articulated a collateral-claim exception. 424 U.S. 319, 330 (1976). The court in *Mathews* permitted a plaintiff to bring a procedural due process claim requesting an evidentiary hearing before the termination of disability benefits. *Id.* at 330–32. *Mathews* explains that there are nonwaivable and waivable jurisdictional elements. The nonwaivable requirement is that a claim must be presented to the administrative agency. *Id.* at 329. The waivable requirement is that administrative remedies be exhausted. *Id.* As to the waivable element, *Mathews* recognizes that “the Secretary may waive the exhaustion requirement if he satisfies himself, at any stage of the administrative process, that no further review is warranted either because the internal needs of the agency are fulfilled or because the relief that is sought is beyond his power to confer.” *Id.* at 330. The court further recognized that “cases may arise where a claimant’s interest in having a particular issue resolved promptly is so great that deference to the agency’s judgment is inappropriate.” Therefore, a party may generally bring a claim in federal court when that “constitutional challenge is entirely collateral to [its] substantive claim of entitlement.” *Id.*

The Fourth Circuit has addressed a similar jurisdictional question in *Ram v. Heckler*, 792 F.2d 444 (4th Cir. 1986). In *Ram*, the plaintiff filed an action to stay a suspension of his Medicare provider status “pending an administrative hearing to determine whether he could properly be suspended and, if so, whether a shorter period of suspension was appropriate.” *Id.* at 445. The plaintiff prevailed at the district court level, and the Government appealed, contending that the district court lacked jurisdiction to issue the stay. *Id.* at 446. The Fourth Circuit held:

The district court properly applied *Mathews v. Eldridge*, to determine whether the exhaustion requirement of 42 U.S.C. § 405(g) precludes jurisdiction in this case. Ram satisfies an essential jurisdictional requirement of *Mathews v. Eldridge*. His claim that he should not be suspended or that he should not be suspended for a period as long as one year has been presented to the Secretary. In *Mathews v. Eldridge* the Court also ruled that the exhaustion requirement of section 405(g) does not apply to a due process claim “entirely collateral” to a substantive claim, if the plaintiff has raised “at least a colorable claim” that erroneous deprivation prior to exhaustion of administrative remedies would harm him in a way that could not be recompensed.

Id. (quoting *Mathews*, 424 U.S. at 330–31) (internal citations omitted).

Here, the nonwaivable jurisdictional element has been satisfied, as Plaintiff has presented a claim to Defendants and pursued three levels of administrative appeals. Furthermore, Plaintiff’s claims in this matter are entirely collateral to the issues of whether it will ultimately succeed on its administrative appeals, and Plaintiff has raised a colorable claim that erroneous deprivation, by way of recoupment, prior to exhaustion of administrative remedies would harm it in a way that could not be compensated. Therefore, the Court finds that it has jurisdiction to decide this matter.

II. Likelihood of Success on the Merits

Plaintiff contends that it is likely to prevail on its underlying procedural due process claim because Defendants continue to recoup large sums of money without providing Plaintiff with an ALJ hearing during the time period mandated by statute. Courts look at three factors when determining whether a procedural due process violation has occurred: “First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government’s interest, including the function involved and the fiscal and administrative

burdens that the additional or substitute procedural requirement would entail.” *Mathews*, 424 U.S. at 335.

Defendants contend that the Fourth Circuit has already decided the due process issue in this case, relying on *Cumberland County Hospital System, Inc. v. Burwell*, 816 F.3d 48 (4th Cir. 2016). In *Cumberland County*, a health system brought an action for a writ of mandamus, seeking a court order that HHS provide an immediate ALJ hearing. *Id.* at 49–50. The Fourth Circuit concluded, “[w]hile we agree that the delay in the administrative process for Medicare reimbursement is incontrovertibly grotesque, the Medicare Act does not guarantee a healthcare provider a hearing before an ALJ within 90 days” *Id.* Instead, the court noted that the regulations provide for escalation when an administrative body does not meet its deadlines. *Id.* The court, noting that “[m]andamus is a ‘drastic’ remedy that must be reserved for ‘extraordinary situations’ involving the performance of official acts or duties,” declined to issue a writ of mandamus. *Id.* at 52 (quoting *Kerr v. U.S. Dist. Court for the N. Dist. of Cal.*, 426 U.S. 394, 402 (1976)).

In so finding, the Court rejected plaintiff’s argument “that the Medicare Act gives it a clear and indisputable right to have its appeals decided within 90 days and that it imposes on the Secretary a clear duty to accomplish that.” *Id.* at 52. Emphasizing the escalation process, the court did address due process concerns in dicta:

The Hospital System argues that this interpretation of the administrative process is unreasonable as it results in a process that provides it the “terrible choice” of deciding whether to “waive its right to due process” or to “suffer interminably until the Secretary feels like affording [it] a hearing. Its due process argument is based on its presumption that, in bypassing the ALJ hearing, it would be denying itself the opportunity to create a full administrative record at the ALJ hearing, thereby leaving itself without a record for judicial review.

The Medicare Act, however, does not support the Hospital System's presumptions. The implementing regulations provide that a healthcare provider may submit "any" evidence it wishes at the QIC redetermination stage, an earlier stage at which the Hospital System has not claimed delay. Thus, healthcare providers could, in anticipation of delays at the ALJ stage and beyond, create their record at the QIC stage and therefore escalate their claims to the courts within a period of months. Moreover, it is not clear that the Hospital System would have, as it assumes, a right to introduce new evidence during an ALJ hearing even if it had the benefit of the hearing.

Id. at 55–56 (internal citations omitted). Based on *Cumberland County*, the Court is unquestionably prohibited from ordering Defendants to provide Plaintiff with an ALJ hearing. But *Cumberland County*'s above quoted dicta on due process concerns did not involve a challenge to ongoing recoupment during the pendency of a provider's wait for an ALJ hearing.

Plaintiff makes a compelling argument here that the ALJ stage of the appellate process is the most important to providers, as it provides the first opportunity for Plaintiff to cross examine Defendants' witnesses and examine the evidence used to formulate the statistical sample. See ECF No. 16 at 2 (citing 42 C.F.R. § 405.1000(b)).⁵ Although the *Cumberland County* court, in dicta, cast doubt on whether a provider could submit new evidence at an ALJ hearing, the regulations make clear that providers can submit new evidence under certain circumstances. See 42 C.F.R. § 405.1018 (noting that the prohibition on new evidence does not apply to oral testimony, including cross examination, given at the hearing); 42 C.F.R. § 405.1028 (permitting the introduction of new evidence at the ALJ hearing when a provider demonstrates good cause).

⁵ "At the hearing, the parties may submit evidence (subject to the restrictions in § 405.1018 and § 405.1028), examine the evidence used in making the determination under review, and present and/or question witnesses." 42 C.F.R. § 405.1000(b).

Because *Cumberland County* was decided in a different procedural posture than the case at bar and did not involve a procedural due process claim where there was ongoing recoupment, the Court finds that *Cumberland County* is not controlling. Therefore, the Court must analyze the procedural due process challenge under the factors outlined above.

As to the first factor, the private interest that is affected is Plaintiff's very existence and financial stability. "To have a property interest in a benefit, a person clearly must have more than an abstract need or desire for it. He must have more than a unilateral expectation of it. He must, instead, have a legitimate claim of entitlement to it. It is a purpose of the ancient institution of property to protect those claims upon which people rely in their daily lives, reliance that must not be arbitrarily undermined." *Bd. of Regents of State Colleges v. Roth*, 408 U.S. 564, 577 (1972). Plaintiff certainly has a property interest in the ongoing Medicare payments for services rendered to patients.⁶ See, e.g., *Adams EMS, Inc. v. Azar*, No. H-18-1443, 2018 WL 3377787, at *4 (S.D. Tex. July 11, 2018) ("Adams EMS has a property interest in receiving the Medicare payments it has earned for its ambulance services."); *Family Rehab., Inc. v. Azar*, No. 3:17-cv-3008-K, 2018 WL 3155911, at *4 (N.D. Tex. June 28, 2018) ("Family Rehab has a property interest in the Medicare payments for services rendered.").

Second, the risk of the erroneous deprivation of this private interest absent an ALJ hearing is great. Plaintiff offers evidence that the "Health and Human Services Office of Inspector General found that claim denials associated with these alleged overpayments

⁶ Indeed, there is no allegation that any of the claims for which payment is being withheld during the recoupment process are fraudulent.

are overturned wholly or partially at the ALJ level 60% of the time." ECF No. 16 at 5. Although Plaintiff can escalate its appeal to the DAB, it would be deprived of important procedural safeguards inherent to the ALJ hearing, namely to test the validity of Defendants' statistical sample in an evidentiary hearing before an independent arbiter. Plaintiff has offered evidence from an expert applied statistician that "the extrapolation employed by CMS is deeply flawed, deficient, and totally unreliable." ECF No. 5-4 at 3. Indeed, the expert reviewed the sampling information provided by Defendants and "was unable to ascertain [Defendant's] sample size methodology, if any, from the documents [he] reviewed, including the methodology used to determine the sample size for each strata" as that information was not provided by Defendants. *Id.* at 14. Based on this expert report, Plaintiff contends that it "must cross-examine Defendants' analyst to challenge the accuracy of the data on which he relied and uncover the fallacies of his assumptions, as part of examining the evidence undergirding Defendants' overpayment decision." ECF No. 16 at 3. Without the opportunity to cross examine Defendants' analyst and present other evidence at a hearing, Plaintiff contends that it will lose the ability to meaningfully challenge Defendants statistical sample through the escalation process. *Id.*

Although the Fourth Circuit has found that the language requiring the ALJ to hear an appeal and render a decision within 90 days is not mandatory,⁷ the Court holds that Plaintiff will forego important constitutional safeguards if they are forced to escalate beyond the ALJ while the recoupment process is ongoing. Cross examination at a de novo hearing before an independent arbiter may very well be the only means to obtain

⁷ A number of courts have disagreed with the Fourth Circuit on this issue. See, e.g., *Am. Hosp. Ass'n*, 812 F.3d 183, 190–91 (D.C. Cir. 2016) (finding the 90-day period to be mandatory and holding that escalation does not suffice to meet the statutory requirement).

the evidence needed to vindicate Plaintiff's property interest, and the *only* opportunity for this cross examination is at the ALJ hearing. See 42 C.F.R. § 405.1018. This right is all the more important given the high rate of reversals at ALJ hearings. See, e.g., *Am. Hosp. Ass'n v. Burwell*, 812 F.3d 183, 188 (D.C. Cir. 2016) (noting that a 2014 survey conducted by the American Hospital Association indicated that 66% of RAC denials were reversed by an ALJ and acknowledging that "even government counsel conceded at oral argument that 43% of ALJ appeals (including from RAC and non-RAC denials) succeed"). As the D.C. Circuit found, "[t]his reversal rate is hardly negligible." *Id.* In light of these statistics and the ongoing recoupment that is jeopardizing Plaintiff's very existence, the Court finds that the escalation process does not provide adequate due process, as the risk of erroneous deprivation of Plaintiff's property interest is too great absent the opportunity for cross examination before an impartial arbiter. See, e.g., *Family Rehab., Inc.*, 2018 WL 3155911, at *5 (noting the importance of an evidentiary hearing and finding "[e]scalation does not provide a remedy to the backlogged ALJs because it does not provide adequate due process").

This holding is bolstered by the fact that the QIC has already reversed a number of denials in this case. As Plaintiff's expert noted in his report, "11 of the 40 claims audited by the ZPIC were reversed in favor of [Plaintiff] at the reconsideration level. It . . . is commonly accepted within the statistical community that changing the number of claims with overpayment amounts within a sample will always result in a change to the overpayment statistics, including the mean, confidence interval and precision ratio. It would be all but impossible for the extrapolation to remain the same considering these findings." ECF No. 5-4 at 40. Put simply, the QIC has already reversed a number of

claims that were allegedly included in, or formed the basis of, Defendants' statistical sample, which calls into question the validity of Defendants' overpayment calculations. Defendants submitted a Sur Reply, which contained, inter alia, the declaration of an employee of Palmetto GBA, which states "[t]he only claims reversed in Plaintiff's favor in that [QIC] reconsideration decision were part of a preliminary audit that did not entail the use of sampling or extrapolation." ECF No. 26 at 1–2. Therefore, the parties clearly disagree about the effect of the QIC's decision, which further underscores the need for an evidentiary hearing to appropriately adjudicate Plaintiff's appeal. The Court, of course, takes no position on the merits of Plaintiff's appeal or Defendants' defenses; however, the nature of this dispute highlights the risk of erroneous deprivation of Plaintiff's property rights if Plaintiff is forced to escalate so as to avoid bankruptcy and underscores the importance of an evidentiary hearing where the parties can present evidence and cross-examine witnesses. As the Supreme Court of the United States has repeatedly noted, "cross-examination is the 'greatest legal engine ever invented for the discovery of truth.'" *Kentucky v. Stincer*, 482 U.S. 730, 736 (1987) (quoting *California v. Green*, 399 U.S. 149, 158 (1970)).

Finally, Plaintiff is not seeking any additional or substitute safeguards that would lead to administrative or financial burdens on the Government. For example, Plaintiff is not asking the Court to order Defendants to provide it with an ALJ hearing. Plaintiff is simply asking that the Government not deprive it of money that it has earned when the Government cannot comply with its own procedural requirements in a timely manner. This will not lead to any measurable administrative or financial burdens on the

Government, particularly because Defendants can still recoup any remainder of what they may be owed if Plaintiff's eventual ALJ appeals are unsuccessful.

The Court acknowledges that this case presents a very close question in light of *Cumberland County*; however, Plaintiff has presented a compelling case that its procedural due process rights are being violated by the combination of the outrageous delay in its administrative appeals and Defendants' ongoing recoupment. The Court has closely examined *Cumberland County*, and finds that the facts of this case are distinguishable. Accordingly, the Court finds that Plaintiff has made a clear showing of its likelihood of success on the merits.

III. Irreparable Harm

Plaintiff has complied with the administrative appeals process and has been waiting more than two years for a hearing before an ALJ. During that time, Plaintiff has lost an estimated \$6,000,000 in gross revenue, and its owner, Dr. Steven McKay, has contributed more than \$1,300,000 in capital contributions in order to keep the business operational. ECF No. 5-2 at 4. Additionally, Plaintiff has been forced to terminate twenty four employees in light of its dwindling gross revenue.⁸ Plaintiff's share of the applicable healthcare market has "shrunk precipitously." *Id.* at 3. Plaintiff's Chief Financial Officer attested that, "[i]f such recoupment continues, it will irreparably harm [Plaintiff], and [it] will be forced to close [its] doors and declare bankruptcy imminently." *Id.* at 4.

Despite this, Defendants contend that Plaintiff does not satisfy this element of the preliminary injunction standard. Essentially Defendants claim Plaintiff should enroll in a monthly payment plan to mitigate any alleged harm. While the Court acknowledges that

⁸ In 2017, Plaintiff's gross revenue was down 63% compared to 2014. ECF No. 5-2 at 3.

Medicare's regulations do provide for extended repayment schedules ("ERS") in certain cases, Defendants' argument misses the point. Plaintiff has offered evidence that it would go bankrupt absent the issuance of an injunction. Certainly, that satisfies this element of the preliminary injunction standard. Moreover, Defendants suggestion that Plaintiff obtain an ERS is dubious at best, as the regulations provide "CMS or its contractor is prohibited from granting an ERS to a provider or supplier if there is reason to suspect the provider or supplier may file for bankruptcy, cease to do business, discontinue participation in the Medicare program, or there is an indication of fraud or abuse committed against the Medicare program." 42 C.F.R. § 401.607(c)(iv).

Accordingly, the Court finds the threat of bankruptcy and severe financial damage in this case meets the requirements of establishing a substantial threat of immediate and irreparable harm for which no adequate remedy at law exists. See *Doran v. Salem Inn, Inc.*, 422 U.S. 922, 932 (1975) ("[T]hese respondents alleged (and petitioner did not deny) that absent preliminary relief they would suffer a substantial loss of business and perhaps even bankruptcy. Certainly the latter type of injury sufficiently meets the standards for granting interim relief, for otherwise a favorable final judgment might well be useless."); see also *Hughes Network Sys., Inc. v. InterDigital Commc'n Corp.*, 17 F.3d 691, 694 (4th Cir. 1994) ("Even if a loss can be compensated by money damages at judgment, however, extraordinary circumstances may give rise to the irreparable harm required for a preliminary injunction. For example . . . irreparable harm may still exist where the moving party's business cannot survive absent a preliminary injunction" (citing *Roland Mach. Co. v. Dresser Indus., Inc.*, 749 F.2d 380, 386 (7th Cir. 1984))).

Additionally, "[i]t has been repeatedly recognized by the federal courts that violation of constitutional rights constitutes irreparable injury as a matter of law." *Springtree Apartments, ALPIC v. Livingston Parish Council*, 207 F. Supp. 2d 507, 515 (M.D. La. 2001) (citation omitted); cf. *Elrod v. Burns*, 427 U.S. 347, 373–74 (1976) ("The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury") (citation omitted). Here, the Court has found that Plaintiff is likely to succeed on the merits of its procedural due process claim. This finding, combined with the tangible, immediate, and irreparable financial harm Plaintiff will suffer absent injunctive relief, satisfies the requirement of irreparable harm.

IV. Balance of the Equities

Absent relief, Plaintiff alleges that it will go bankrupt, employees will lose their jobs, and patients will lose access to much needed healthcare. Conversely, Defendants contend "Plaintiff cannot show that the Medicare program would not suffer harm from the entry of an injunction against further Medicare recoupment. Defendants' interest in carrying out duties entrusted to them by Congress outweighs Plaintiff's interest in receiving special relief." ECF No. 23 at 17–18. Under the facts of this case, the Court finds that the harm to Defendants is substantially outweighed by the harm that Plaintiff will suffer if recoupment continues while it is deprived of a hearing before an ALJ. Defendants are correct that they have a manifest interest in carrying out the duties entrusted to them by Congress; however the Medicare appeals system and the recoupment provisions clearly envision a process that is far more streamlined than the current grotesquely backlogged system. Plaintiff's factual showing as to the harm it will

suffer—namely bankruptcy—substantially outweighs any harm Defendants may suffer by delaying recoupment until Plaintiff’s ALJ hearing.

V. Public Interest

The quality of the healthcare services Plaintiff provides to an underserved community is not at issue in this case, only the reimbursement for those services. To that end, Plaintiff has offered reliable evidence that it will have to shutter its doors if recoupment continues unabated. If Plaintiff files for bankruptcy, a significant patient population will have to find new medical providers. There is no question that the public at large—particularly the vulnerable Medicare population—will be better served by more, rather than less, access to healthcare. Defendants contend that Plaintiff is seeking special treatment among a system of nearly two million Medicare providers. That is not so, however, as Plaintiff merely seeks a temporary halt to recoupment until it gets the ALJ hearing that it is entitled to under the statutory scheme. As such, Plaintiff has shown a likelihood of success on the merits of its procedural due process claim, and “it is always in the public interest to prevent the violation of a party’s constitutional rights.” *G & V Lounge, Inc. v. Michigan Liquor Control Comm’n*, 23 F.3d 1071, 1079 (6th Cir. 1994) (citations omitted). Accordingly, the Court concludes the public interest will be served by granting the preliminary injunction in order to allow Plaintiff to continue to provide these much needed services.

VI. Bond Requirement

In its discretion, the Court waives the bond requirement for Plaintiff. See *Pashby v. Delia*, 709 F.3d 307, 332 (4th Cir. 2013) (“[T]he district court retains the discretion to set the bond amount as it sees fit or waive the security requirement.” (citations omitted)).

Under the circumstances of this case, the Court finds that the Defendants will suffer no meaningful harm, as they can continue their ongoing recoupment efforts immediately if they ultimately prevail on the merits. See *Hoechst Diafoil Co. v. Nan Ya Plastics Corp.*, 174 F.3d 411, 421 n.3 (4th Cir. 1999) ("In fixing the amount of an injunction bond, the district court should be guided by the purpose underlying Rule 65(c), which is to provide a mechanism for reimbursing an enjoined party for harm it suffers as a result of an improvidently issued injunction or restraining order.").

CONCLUSION

For the reasons detailed above, the Court **GRANTS** Plaintiff's Motion for Preliminary Injunction, ECF No. 5, and **ORDERS** that Defendants are hereby restrained and enjoined from withholding Medicare payments to Plaintiff to effectuate the recoupment of any alleged overpayments. The Court **FURTHER ORDERS** that Defendants are hereby restrained and enjoined from attempting or initiating any other collection efforts, such as referral through the Department of the Treasury or a third-party collection agency. This preliminary injunction does not enjoin Defendants from withholding Medicare payments for any new alleged claims of overpayments that may occur in the intervening time.

IT IS SO ORDERED.

s/Donald C. Coggins, Jr.
United States District Judge

September 27, 2018
Spartanburg, South Carolina